

# Notice of Allowability

Application No.

10/614,275

Examiner

Lynn Bristol

Applicant(s)

HE ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response of 11/23/07.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER

### **DETAILED ACTION**

1. Claims 1-11 are all the pending claims for this application.
2. Claims 12-45, 48-64 were cancelled in the Response of 11/23/07.
3. Claims 1-11 are all the pending claims under examination and are in condition for allowance.

#### **Withdrawal of Objections**

4. The objection to the specification for the improper use of trademarks is withdrawn. The amendment to the specification on p. 2 of the Response of 11/23/07 obviates the objection.

Applicants' comments on p. 3 of the Response of 11/23/07 are acknowledged.

#### **Withdrawal of Rejections**

##### ***Claim Rejections - 35 USC § 112, second paragraph***

5. The rejection of Claims 23-45 and 48-62 under 35 U.S.C. 112, second paragraph for the recitation "wherein the isolated polypeptide regulates transcription in prostate tissue" is withdrawn in view of the cancelled claims.

Applicants' comments on p. 5 of the Response of 11/23/07 are acknowledged.

##### ***Claims - 35 USC § 112, first paragraph***

##### ***Biological Deposit Requirement***

6. The rejection of Claims 12-22, 34-44 and 54-62 under 35 U.S.C. § 112, first

paragraph, for failing to comply with the requirements for a biological deposit under the terms of the Budapest Treaty is withdrawn in view of the cancelled claims.

Applicants' comments on p. 3 of the Response of 11/23/07 are acknowledged.

***Written Description Requirements***

7. The rejection of Claims 23-45 and 48-62 under 35 U.S.C. 112, first paragraph, as drawn to polypeptides comprising contiguous regions of 30 or 50 amino acid residues of SEQ ID NO:2 or 4 or from a full-length protein encoded by DNA of ATCC deposit No. 209005 or 209006, or having at least 95% sequence identity to amino acid residues 1-234 of SEQ ID NO:2 or from a full-length protein encoded by DNA of ATCC deposit No. 209005 or 209006 is withdrawn in view of the cancelled claims.

Applicants' comments on p. 3 of the Response of 11/23/07 are acknowledged.

***Enablement Requirements***

8. The rejection of Claims 1-45 and 48-64 under 35 U.S.C. 112, first paragraph, as not being enabled for making or using a full-length human (or murine) NKX3.1 protein of SEQ ID NO:2 or 4 or a full length NKX3.1 protein encoded by genomic DNA or cDNA of ATCC Deposit No.209005 and 209006 or proteins having at least 95 % identity with the protein of SEQ ID NO:2 or 4 or peptides comprising 30 or 50 contiguous amino acids of SEQ ID NO:2 or 4 is withdrawn.

The rejection of Claims 12-45 and 48-64 is withdrawn in view of the cancelled claims.

The rejection of Claims 1-11 is withdrawn in view of Applicants' allegations on p. 3 of the Response of 11/23/07. Applicants' aver:

"The evidence of record shows that NKX3.1 proteins have been expressed and used in the art, including for use in biological assays. See, e.g., Steadman et al. (ref A97)" and "Applicants need only enable one use of the claimed invention (MPEP 2164.01 (c))."

Upon further consideration of the evidence of record: the Steadman reference, the disclosure in the specification and the field of art for the NKX3.1 family of proteins at the time of filing, the rejection is withdrawn. The Examiner's decision is further based on the following supporting references showing that the NKX3.1 family of proteins possess homoeobox domains and have demonstrated transcriptional activity:

Kim et al. PNAS 86:7716-7720 (1989); cited in the IDS of 8/15/06

He et al. Genomics 43:69-77 (1997); cited in the IDS of 8/15/06

Sciavolino et al. Dev. Dyn. 209:127-138 (1997); cited in the PTO form 892 of 9/20/06

Bierberich et al. JBC 271:31779-31782 (1996); cited in the PTO form 892 of 9/20/06

### ***Claims - 35 USC § 102***

9. The rejection of Claim 64 under 35 U.S.C. 102(a) as being anticipated by Sciavolino et al. (Developmental Dynamics 209:127-138 (May 1997)) is withdrawn in view of the cancelled claim.

Applicants' comments on p. 3 of the Response of 11/23/07 are acknowledged.

10. The rejection of Claim 64 under 35 U.S.C. 102(a) (*formerly 102(b)*) as being anticipated by Bieberich et al. (J. Biol. Chem. 271:31779-31782 (December 13, 1996)) is withdrawn in view of the cancelled claim.

Applicants' comments on p. 3 of the Response of 11/23/07 are acknowledged.

**EXAMINER'S STATEMENT FOR REASONS FOR ALLOWANCE**

11. The following is an examiner's statement of reasons for allowance:

The human homeobox-containing NKX3.1 protein of SEQ ID NO: 2 (residues 1-234), residues 2-234 of SEQ ID NO:2, SEQ ID NO4, and residues 2-234 of SEQ ID NO:4 is found to be free of prior art. The claimed NKX3.1 proteins in containing homeobox domains would inherently bind to nucleic acid consensus sequences and as shown in Steadman et al., the human NKX3.1 protein bound in vitro DNA consensus sequence. Therefore NKX3.1 is considered to provide transcriptional regulation of gene expression, and because of the noted absence or loss of the protein in some prostate cancer patients, NKX3.1 transcription may be critical in prostate cancer pathogenesis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

12. Claims 1-11 are in condition for allowance.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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